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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,731	10/25/2006	Stefan Leyen	DNAG-310	1384
24972 7590 11/10/2008 FULBRIGHT & JAWORSKI, LLP			EXAMINER	
666 FIFTH AVE		STEWART, JASON-DENNIS NEILKEN		
NEW YORK, NY 10103-3198			ART UNIT	PAPER NUMBER
			3738	
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			11/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/549,731 LEYEN ET AL. Office Action Summary Examiner Art Unit JASON-DENNIS STEWART 3738 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 18 September 2008. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 35-45 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 35-45 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 18 September 2008 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

PTOL-326 (Rev. 08-06)

1) Notice of References Cited (PTO-892)

Information Disclosure Statement(s) (PTO/S5/08)
 Paper No(s)/Mail Date \_\_\_\_\_\_.

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

#### DETAILED ACTION

The following is a Non-final Office action in response to communications received on 09/18/2008. Claims 1-34 are cancelled. Claims 35-45 are added. Therefore, Claims 35-45 are pending and addressed below.

#### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/18/2008 has been entered.

## Drawings

The new drawing (Fig. 5) was received on 9/18/08. This drawing is not acceptable because the use of "radius" is not clear since the term defines a line and the drawing submitted is showing the line extending from some center point of space which Applicant cannot refer to. It is not clear if Applicant means radius to define the depth of the notch from the inner surface of the cup.

Application/Control Number: 10/549,731 Page 3

Art Unit: 3738

#### Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 35,45 recite the limitation "the notch radius" in lines 6,5 respectively of the claims. It is unclear from the drawings and the specification what the Applicant designates as the "radius" as this term is used to suggest a distance and not a point as is shown in Fig. 5 of the instant specification.

Does Applicant mean to use the term "radius" as the depth of the notch? Radius seems to be indefinite because it is used with the term notch of which has a certain depth, but the radius can extend beyond that depth to the center point of where it is measured from

## Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Art Unit: 3738

4. Claims 35-41, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunz et al. WO 01/05338 in view of Pope et al. (6,676,704) further in view of McLean et al. 2004/0054418.

 Regarding Claims 35-38, Bunz discloses a hip joint prosthesis comprising an inner sliding cup made of ceramic material that is surrounded on its outside by a plastic covering (abstract).

However, Bunz does not disclose surface semicircular depressions with a notch radius of more than .5mm arranged circumferentially on the outside of the sliding cup.

Pope discloses a substrate for attachment to a femoral head and an acetabular comprising of spherical segment depressions with a diameter from .001 in. up to .750 in. (col. 43, II. 15-35), undulating in section, and circumferentially arranged (fig. 3c) for the purpose of creating a mechanical interlock between adjacent layers of the hip prosthesis (col. 41, II. 23-25).

It would have been obvious to one of ordinary skill in the art at the time of the invention combine the sliding cup of the sandwich insert of Bunz with the undulating depressions of Pope in order to achieve a mechanical interlock as taught by Pope (col. 41, II. 23-25).

Bunz in view of Pope discloses the invention as claimed and as discussed above. However, Bunz in view of Pope does not disclose a metal shell around the plastic covering.

Art Unit: 3738

McLean discloses a hip prosthesis comprising a metal shell with a polyethylene liner adapted to fit tightly in the shell (paragraph 3).

It should be noted that the use of plastic liner inside or metal shells is widely known and practiced in the art. It would have been obvious to one of ordinary skill in the art to modify the device of Bunz with a metal shell in order to provide articulating surface for a femoral head as disclosed my McLean (paragraph 3).

- Regarding Claim 29, Bunz illustrates a sliding cup (1) having a stepped structural form on its outside (fig. 2).
- Regarding Claim 30, Bunz illustrates the plastic covering embracing the sliding cup at its pin end (fig. 2).
- Regarding Claim 31, Bunz illustrates a collar of the plastic covering 5 that rests on the upper side of the sliding cup and covers almost half of the upper edge (fig. 2).
- Regarding Claim 33, Bunz in view of Pope discloses the invention as claimed and as discussed above. However, Bunz as modified by Pope do not disclose an eccentric relationship between the inner and outer form of the sliding cup.

McLean et al. discloses an eccentric relationship between the inner surface 30 and the outer surface 26 of an articulating surface shell in order to improve migration and other properties of the prosthesis.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sliding cup of Bunz in view of Pope with the eccentric relationship of McLean in order to optimize articulating wear properties of the sliding cup relative to the femoral head.

Art Unit: 3738

- 10. Regarding Claim 34, Bunz in view Pope and further in view of McLean discloses the invention as claimed and discussed above, however Bunz does not positively recite the range claimed in Claim 34. It has been held that "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." In re Peterson, see MPEP 2144.05, Part II. section A.
- 11. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bunz et al. WO 01/05338 in view of Pope et al. '704 in view of McLean et al. 2004/0054418 and further in view of Teinturier (5,041,140).

Bunz in view of Pope in view of McLean discloses the invention as claimed and as discussed above. However, Bunz in view of Pope does not disclose a press fit between the sliding cup and the plastic covering.

Teinturier teaches a press fit between a plastic cup 42 and a metal shell in order to allow the acetabulum unit to adapt to deformations of the skeleton and adapt to them (col. 4, II. 59-62).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sliding cup of Bunz in view of Pope by press fitting it into the plastic covering as taught by Teinturier in order to allow for deformation of the skeleton by the hip prosthesis.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bunz et
 WO 01/05338 in view of Pope et al. (6,676,704).

Art Unit: 3738

 Bunz discloses a hip joint prosthesis comprising an inner sliding cup made of ceramic material that is surrounded on its outside by a plastic covering (abstract).

However, Bunz does not disclose surface semicircular depressions with a notch radius of more than .5mm arranged circumferentially on the outside of the sliding cup.

Pope discloses a substrate for attachment to a femoral head and an acetabular comprising of spherical segment depressions with a diameter from .001 in. up to .750 in. (col. 43, II. 15-35), undulating in section, and circumferentially arranged (fig. 3c) for the purpose of creating a mechanical interlock between adjacent layers of the hip prosthesis (col. 41, II. 23-25).

It would have been obvious to one of ordinary skill in the art at the time of the invention combine the sliding cup of the sandwich insert of Bunz with the undulating depressions of Pope in order to achieve a mechanical interlock as taught by Pope (col. 41, Il. 23-25).

## Response to Arguments

14. Applicant's arguments filed 09/18/2008 have been fully considered but they are not persuasive. Applicant argues that there is no motivation to modify the device of Bunz with depressions. The Examiner respectfully disagrees. There are many ways to achieve mechanical interlock between two layers in a hip prosthesis. Pope is used as a teaching to show that used depressions and corresponding protrusions is practiced in the art. Furthermore, the mechanical interlock achieved by Bunz is not necessarily the same as it would be if the depressions were added to the surface of the sliding cup.

Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON-DENNIS STEWART whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 FST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS /Jason-Dennis Stewart/ Examiner, Art Unit 3738

/Brian E Pellegrino/ Primary Examiner, Art Unit 3738